IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Understanding Active Pharmaceutical Ingredients (APIs)

16-17 July 2025
+ 19-20 November 2025

This course will cover key terminology, the EU and USA regulatory framework, Good Manufacturing Practice (GMP) requirements including controls and validation, and consider Good Distribution Practice (GDP) and how to manage your supply chain.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

An active pharmaceutical ingredient (API) or drug substance is any substance or mixture of substances intended to be used in the manufacture of a medicinal product, which is intended to furnish pharmacological activity, or have another direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or affect the structure and function of the body.

This course has been designed to provide attendees with a fundamental understanding of best practice and the regulatory environment applicable to active pharmaceutical ingredients in the pharmaceutical industry. It will cover key terminology, the EU and USA regulatory framework, Good Manufacturing Practice (GMP) requirements including controls and validation, and consider Good Distribution Practice (GDP) and how to manage your supply chain. Practical exercises will form part of the course to aid the learning process.

This is an essential and valuable introduction to the manufacture of APIs.

Benefits of attending

- **Gain** a comprehensive overview of the API regulatory framework
- **Enhance** your understanding of the key terms used in API manufacture
- **Recognise** how Good Manufacturing Practices (GMP) apply to API synthesis
- **Understand** the different approaches between small molecule and large molecule processing
- **Learn** how to manage the risk associated with your supply chain

Who should attend?

- New entrants to those individuals working in a GxP environment
- Quality management manufacturing specialists
- Regulatory compliance specialists
- Pharmaceutical technical professionals
- Pharmaceutical professionals looking to enhance their Continuous Professional Development (CPD)

Programme

Day 1

Introduction to APIs

- Terminology and acronyms
- Globalisation
- Introduction to the regulatory framework

Methods and equipment – Part 1

- Chemical synthesis
- Reactors
- Isolation
- Drying
- Exercise: managing particle size

Methods and equipment – Part 2

- Biological
- Fermentation
- Harvesting
- Exercise: impurities

Good Manufacturing Practice (GMP)

- Requirements
- Regulations
- EU
- FDA
- Exercise: similarities and differences

GMP requirements (continued)

- Pharmaceutical Quality System
- Validation and Qualification
- Outsourcing
- Exercise: specialist or generalist

Supply chain considerations

- Falsified Medicines Directive (FMD)
- Good Distribution Practice (GDP) for APIs
- Exercise risk mitigation

Day 2

Introduction and recap

Registration aspects of production and control

- The registration process
- The Common Technical Document (CTD)
- Active substance/drug master files
- Exercise: strategy

Laboratory controls

- Good Quality Control Laboratory Practice (GQCLP)
- Validation
- Stability
- Exercise: data Integrity

Process validation

- Purpose of validation
- General considerations
- Exercise: critical attributes

Cleaning validation

- Cleaning strategy
- Key requirements
- Residues
- Exercise: purpose

API control packaging materials

- What to consider
- Data requirements
- Extraction, interaction, migration and sorption
- Toxicology
- Exercise: environmental factors

Wrap up and Q&A

Presenter

Paul Palmer

Paul R Palmer is a Director / Pharmaceutical Consultant and a practicing EU / UK Qualified Person. He has over 35 years experience in the pharmaceutical industry in the development, manufacture and supply of medicinal products and medical devices.

Throughout his career, Paul has intentionally taken on all opportunities as they arose in order to develop a broad range of knowledge with an in-depth detailed understanding of manufacturing, storage, distribution, research, computerised systems, as well as the facilities and services to support each.

People and systems have always been a core focus, how to ensure best use, optimise and enhance efficiency. He has a level of curiosity rarely displayed in people taking on the qualified person role in pharmaceutical manufacturing. Culture, behaviour and psychology are all significant influences on the systems and processes we implement, but are often ignored.

Paul studied psychology as part of his MSc in 1993 and has always enjoyed observing the world around him with a curiosity that is rarely satisfied.

Course dates

16-17 July 2025	**Live online** 09:30-17:30 **UK (London)** (UTC+01) *Course code 14849*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 11 Jun**
19-20 November 2025	**Live online** 09:30-17:30 **UK (London)** (UTC+00) *Course code 15073*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 15 Oct**

How to book

Online:
ipi.academy/2505

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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